The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MADS LIENDGAARD VIGH,
and HENRIK ANDERSEN

Appeal No. 2006-1923
Application No. 09/255,655

ON BRIEF

Before GRIMES, GREEN, and LEBOVITZ, Administrative Patent Judges.

LEBOVITZ, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to administering D-tagatose to a human in a daily amount of 5-30 grams. The examiner has rejected the claims as anticipated in view of prior art. We have jurisdiction under 35 U.S.C. § 134. We reverse.

Background

D-tagatose is a well-known low-calorie food sweetener that is also a hyperglycemic agent. Specification, page 1, lines 25-28; page 2, lines 1-4. The application describes the discovery that consumption of D-tagatose induces the

production of butyrate by bacteria, stimulating the growth of lactobacilli and lactic acid bacteria in the colon. Id., page 7, lines 20-26. Because these bacteria are beneficial to the health of the colon, D-tagatose is described as a useful food supplement. Id., page 5, line 15-page 6, lines 18; page 7, lines 17-19.

Discussion

1. Claim construction

Claims 13-22 are on appeal. The claims were stated by Appellant to stand or fall together. Brief, page 3, VII.

Claims 13 and 18 are the broadest claims on appeal. They read as follows:

> 13. A method for selectively inducing production of butyrate by bacteria in the colon of a human in need thereof comprising administering D-tagatose to said human in a daily amount of 5-30 grams to selectively induce production of butyrate.
>
> 18. A method for selectively stimulating growth of lactobacilli and lactic acid bacteria in the colon of a human in need thereof comprising administering D-tagatose to a human in a daily amount of 5-30 grams to selectively stimulate growth of lactobacilli and lactic bacteria in the colon.

Claim 13 requires that the administration of the "daily amount of 5-30 grams" of D-tagatose induce "production of butyrate by bacteria in the colon of a human in need thereof." Claim 18 requires that the same dosage of D-tagatose stimulate growth of bacteria "in the colon of a human in need thereof." The claims do not indicate what class of humans would be in need of D-tagatose. However, "a person of ordinary skill in the art is deemed to read the claim term

not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Phillips v. AWH Corp., 415 F.3d 1303, 1313, 75 USPQ2d 1321, 1326. (Fed. Cir. 2005). The patent application describes several benefits of D-tagatose to humans, including: to "stimulate the growth of beneficial lactobacilli and lactic acid bacteria in the human colon"; to keep "a healthy balance [of bacteria] in the colon"; and for a "possibly has a colon cancer protective effect." Specification, page 1, lines 13-17; page 7, lines 15-16 and 20-26. In view of these broad benefits, we do not view the class of humans "in need thereof" to be narrowly limited.

The requirement that the daily administration induces butyrate production (claim 13) or stimulates bacteria growth (claim 18) is the intended result of carrying out the claimed step of "administering D-tagatose." Generally, if a limitation only states the result of the claim limitations, it does not constitute a limitation itself. Texas Instruments Inc. v. U.S. Intern. Trade Comm., 988 F.2d 1165, 1172, 26 USPQ2d 1018, 1023 (Fed. Cir. 1993). Thus, we do not construe the claim to require that D-tagatose be administered for the purpose of achieving butyrate production or bacterial growth.

2. Anticipation, 35 U.S.C. § 102(b)

Claims 13-22 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Zehner[1].

[1] Zehner et al. (Zehner), U.S. Pat. No. 5,447,917, issued Sept. 5, 1995.

Zehner describes the oral administration of D-tagatose to treat hyperglycemia and diabetes. Zehner, column 2, lines 20-35; column 3, lines 12-20. According to the patent, D-tagatose has a blood glucose lowering effect and reduces the occurrence of deleterious breakdown products that cause complications associated with hyperglycemia and diabetes. Id., column 2, lines 14-25; column 3, lines 22-column 4, line 10. The effect of D-tagatose on blood glucose and insulin levels was demonstrated in rats that had received 1 gram ("g") of D-tagatose per kilogram ("kg") of body weight. Id., column 2, line 45-column 3, line 10.

The examiner rejected all claims as anticipated, arguing that "Zehner teaches (columns 2-4, claims 1-3) the oral administration of D-tagatose to a human in a dose of 1 g/kg body weight, which encompasses the claimed daily administration of 5-30 grams." Answer, page 3 and 6.

"To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981); Verdegaal Bros., Inc. v. Union Oil Co. of Cal., 814 F.2d 628, 630, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

We agree with Appellant that Zehner does not anticipate the claimed invention. There is no express or inherent disclosure in the Zehner patent of the claimed daily administration of 5-30 grams of D-tagatose. Anticipation requires a showing that each element of the claim is identifiable in a single reference. See, e.g., Perricone v. Medicis Pharm. Corp., 432 F.3d 1368, 1375, 77 USPQ2d 1321, 1325 (Fed. Cir. 2005). With this element lacking, we cannot sustain the examiner's rejection.

After carefully reviewing the Zehner patent, we find there is no information in it that would indicate that the disclosed dosage of 1 gram of D-tagatose per kilogram of body weight is a daily dosage. Example 1 establishes that a single dose of D-tagatose provided at 1 g/kg to rats had an anti-hyperglycemic effect that relieved the requirement for insulin. Zehner, column 3, line 10. Based on this finding, Zehner suggests it for humans, and describes administering it in edible formulations or as a unit dosage. Id., column 3, lines 11-21. However, as Appellant pointed out on page 6 of the Brief, there is no teaching that would tell the skilled how much to provide a human on a daily basis. See also Reply Brief, page 2.

In the only other example in the patent, rats were given free access ("ad libitum") to food containing 15% by weight of D-tagatose. Id., column 4, lines 13-21. However, there was no disclosure in the patent, or evidence proffered by the examiner, of how much food the rats consumed on a daily basis. The examiner bears the initial burden of showing unpatentability. See, e.g., In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A prima

facie case of anticipation requires a showing that all elements of the claimed invention are present either explicitly or inherently, in the allegedly anticipating prior art reference. The examiner has not satisfied his burden here.

In sum, we find that Zehner is a generic teaching of administering D-tagatose at an effective amount (e.g., 1 g per kg of body weight) for treating hyperglycemia, but with no explicit or inherent disclosure of daily dosage that would meet the claim limitations. For this reason, we fully agree with Appellant that Zehner is not an anticipatory disclosure of the claimed subject matter.

Moreover, to meet the claimed daily amount of 5-30 grams of D-tagatose using Zehner's dosage of 1 g D-tagatose per kg of body weight, a human weighing from 5 kg to 30 kg would be the required subject. This translates into a body weight of 11 (1 kg = 2.2 lbs) lbs to 66[2] lbs, the normal weight of a baby to a young child. Zehner does not specifically describe treating children with D-tagatose, a necessary teaching for the disclosed dosage amount of 1 gm/kg body weight to anticipate the claimed invention. Thus, because body weights of humans vary, a direction to administer 1 g per kilogram of a body weight would not necessarily result in a daily dosage of 5-30 grams. That is, because Zehner does not disclose treating children with D-tagatose, its teachings do not inherently disclose a dosage of 5-30 gm/kg. Inherent anticipation requires that a process "necessarily and inevitably" occur. Schering Corp. v. Geneva Pharmaceuticals, 339 F.3d 1373, 67 USPQ2d 1664 (Fed. Cir. 2003). Zehner does not meet this standard.

[2] In Appellant's Brief on Page 6, they incorrectly characterize 30 kg as being "about 81 pounds."

Summary

We reverse the rejection of claims 13-22 as anticipated by Zehner.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Eric Grimes)
Administrative Patent Judge)
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Lora Green)
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